

REMARKS

Reconsideration and reexamination of this application are respectfully requested.

By this amendment, Applicants cancel claims 9, 10, 35, 36, 38, and 39, and amend claims 1-8, 11-34, and 37, without prejudice to, or disclaimer of, the cancelled or amended subject matter. Claims 1-8, 11-34, and 37 are pending. Applicants reserve the right to prosecute claims directed to the subject matter of the cancelled and amended claims in one or more continuation applications.

The amendments to the claims find support, for example, at page 1, lines 3-5; page 4, line 35 to page 5, line 27, and in the original claims as filed. The amendments do not add new matter.

In the outstanding Office Action the Examiner finally rejected claims 1-39. Applicants submit that the amended claims are in condition for allowance and will address each of the rejections made in the Office Action in turn.

Rejection for Non-Statutory Double Patenting

The Office rejected claims 1-12, 17-18, and 35-37 under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-20 of U.S. Pat. No. 6,183,783 ("the '783 patent"). (Office Action at pages 1-2.) Claims 1-20 of the '783 patent are directed to microcapsules and methods of making microcapsules. In contrast, amended claims 1-8, 10-34, 36, and 37 are directed to a method for administering a therapeutic agent via inhalation by the pulmonary route to a patient. Applicants respectfully submit that claims 1-8, 10-34, 36, and 37 are nonobvious over claims 1-20 of the '783 patent and request that this ground of rejection be withdrawn.

Rejections Under 35 U.S.C. § 102(b)

The Office rejected claims 1-8, 11-14, 16-21, 25, 27, 31, 32, and 34-39 under 35 U.S.C. § 102(b), as allegedly anticipated by WO 98/31346. (Office Action at pages 3-4.) Applicants respectfully traverse this rejection as to the amended claims.

“A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently in a single prior art reference.” *Verdegaal Bros v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987); see also M.P.E.P. § 2131.

As amended, independent claims 1 and 37 are directed to a method for administering an active principle via inhalation by the pulmonary route to a patient. The method comprises providing a biocompatible microparticle consisting of (a) a core consisting of said active principle, and (b) an external layer of at least one coating agent deposited on said core by a supercritical fluid technique. Thus, the core of the microparticles used in the claimed method does not contain coating agent. (This is a necessary result of the coating agent being “deposited on said core by a supercritical fluid technique.”)

As described in the application, the structure of Applicants’ claimed microparticles “distinguishes them from the microparticles of the prior art, which are matricial microspheres obtained using techniques of emulsifying-evaporating solvent, of extracting solvent with aqueous phases or of nebulization drying organic solvent.” (Application at page 4, line 38 to page 5, line 5.) This distinction applies to WO 98/31346. Specifically, WO 98/31346 discloses examples of using a solvent evaporation technique, a double emulsion technique or a spray drying technique to make particles. All of these techniques lead to the formation of particles with a matricial

microsphere structure. (See WO 98/31346 at page 14, lines 1-14; page 27, line 13; page 28, line 10.)

Because WO 98/31346 does not disclose a biocompatible microparticle consisting of (a) a core consisting of said active principle, and (b) an external layer of at least one coating agent deposited on said core by a supercritical fluid technique, as recited by the pending method claims, WO 98/31346 does not disclose every element of the pending method claims. Therefore, WO 98/31346 does not anticipate the pending method claims. See *Verdegaal Bros.*, 814 F.2d at 631 (Fed. Cir. 1987) (“A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently in a single prior art reference.”); see also M.P.E.P. § 2131. Accordingly, Applicants respectfully request that this ground of rejection be withdrawn.

The Office also rejected claims 1-8, 10-13, 17-19, 24, 30, 31, and 35-37 under 35 U.S.C. § 102(b), as allegedly anticipated by EP 0706821. (Office Action at page 4.) “A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently in a single prior art reference.” *Verdegaal Bros v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987); see also M.P.E.P. § 2131. All of Applicants’ pending claims are directed to a method for administering an active principle via inhalation by the pulmonary route to a patient. EP 0706821 does not disclose such a method and, therefore, does not anticipate the pending claims. Applicants respectfully request that this ground of rejection be withdrawn.

The Office also rejected claims 1-12, 17-18, and 35-37 under 35 U.S.C. § 102(b), as allegedly anticipated by FR 2753639. (Office Action at page 4.) “A claim is anticipated only if each and every element as set forth in the claim is found either

expressly or inherently in a single prior art reference.” *Verdegaal Bros v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987); see also M.P.E.P. § 2131. All of Applicants’ pending claims are directed to a method for administering an active principle via inhalation by the pulmonary route to a patient. FR 2753639 does not disclose such a method and, therefore, does not anticipate the pending claims. Applicants respectfully request that this ground of rejection be withdrawn.

The Office also rejected claims 9 and 10 under 35 U.S.C. § 102(b), as allegedly anticipated by WO 96/29998. (Office Action at page 5.) “A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently in a single prior art reference.” *Verdegaal Bros v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987); see also M.P.E.P. § 2131. All of Applicants’ pending claims are directed to a method for administering an active principle via inhalation by the pulmonary route to a patient. WO 96/29998 does not disclose such a method and, therefore, does not anticipate the pending claims. Applicants respectfully request that this ground of rejection be withdrawn.

Rejection Under 35 U.S.C. § 103(a)

The Office rejected claims 15, 19, 20, 22, 23, 25, 26, 28, 29, and 33-39 under 35 U.S.C. § 103(a), as allegedly obvious over WO 98/31346. (Office Action at pages 6-7.) In support of this rejection, the Office states that, while WO 98/31346 does not teach the individual phosphatidylethanolamine, phosphatidylserine, anti-asthmatic agent, and beclametasone recited by the rejected claims, the specifically claimed embodiments would have been obvious. Applicants respectfully disagree with the Office. However, even assuming, for the sake of argument only, that the Office’s position is correct,

because WO 98/31346 fails disclose a biocompatible microparticle consisting of (a) a core consisting of said active principle, and (b) an external layer of at least one coating agent deposited on said core by a supercritical fluid technique, as recited by the pending method claims, WO 98/31346 does not disclose every element of the pending method claims. Furthermore, because WO 98/31346 does not suggest a method for administering an active principle via inhalation by the pulmonary route to a patient, in which the method uses a biocompatible microparticle consisting of (a) a core consisting of said active principle, and (b) an external layer of at least one coating agent deposited on said core by a supercritical fluid technique, as recited by the pending method claims, WO 98/31346 does not render the pending claims obvious. Accordingly, Applicants respectfully request that this ground of rejection be withdrawn.

In view of the foregoing remarks, Applicants submit that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art. Applicants courteously request the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

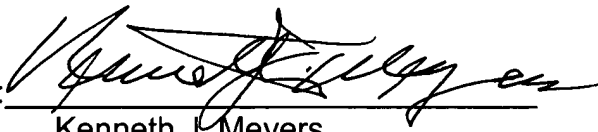
Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

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By:



Kenneth J. Meyers
Reg. No. 25,146